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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,456	09/30/2005	Nitin Bhalachandra Dharmadhikari	053180	3014

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EXAMINER	
CAPAN, ELIZABETH S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,456	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	ELIZABETH S. CAPAN	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/30/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Claims 1-18 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09 May 2007 has been considered by the examiner.

Specification

The abstract of the disclosure is objected to because of typographical errors. Page 3, line 5 should read "being referred to as" instead of "being to referred to as"; on page 3, line 32, the extra space between "agents" and "is" should be deleted. Correction is required. See MPEP § 608.01(b).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 1, 2, 8, and 12-14 are objected to because of the following informalities: Claim 1 has components listed as items (f)-(j); these items should instead be listed as (a)-(e). In claim 2, "a" should be inserted before each of "water soluble polymer", "water

swellable polymer", and "pH-dependent polymer". In claim 8, a space should be inserted between "claim" and "1". In each of claims 12-14, "a" should be inserted before "different beneficial agent". Appropriate correction is required.

Double Patenting

Claims 1-5, 7-8, and 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-15 of copending Application No. 11/946575.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to a programmed drug delivery system comprising a core comprising one or more beneficial agents and one or more pharmaceutically acceptable excipients wherein at least one excipient swells when exposed to an aqueous environment, a core-surrounding coat which is impermeable to the beneficial agent but permeable or impermeable to water, a passageway in the coat, a composition applied so as to cover the passageway, and an optional immediate release composition comprising the same or different beneficial agent. The passageway covering comprises a polymer selected from the group consisting of a water soluble polymer, a water swellable polymer, a pH-dependent polymer, and mixtures thereof. The beneficial agent can be an agent that is susceptible to the gastric environment, is targeted to the intestine for local action, or causes bleeding or irritation of the gastric mucosa. The composition covering the passageway is designed to release the core contents at a

predetermined location in the gastrointestinal tract after oral ingestion. The system can provide delayed or controlled release of the beneficial agent. The system provides for either an immediate release followed by a timed controlled release of the same or different beneficial agent(s), or an immediate release of a beneficial agent followed by a delayed release of another beneficial agent, with the delays being dependent or independent of gastric emptying time.

The copending claims are drawn to a coated tablet oral drug delivery system having a core comprising at least one active ingredient and a swellable composition located in the immediate vicinity of one or more preselected surfaces, and a coating comprising water insoluble polymers and a leachable component (such as the immediate release composition of the instant claims), wherein the coating can be removed from one or more of the preselected surfaces, but not removed from at least one of the surfaces. The coating can be impermeable to the active agent or semipermeable, and an additional pH-dependent coating can be applied. Multiple layers may be present and of the same or different composition. The composition can comprise a controlled release composition, or both immediate and controlled release compositions.

The differences in the two applications arise in the fact that the instant claims require a passageway in the coating, while the copending claims do not. However, the selective removal of the coating from one or more surfaces in the copending application functions as a "passageway" with a covering. Another difference lies in the fact that the copending claims do not explicitly require release delays being

dependent on gastric emptying time. However, this feature is inherent in the copending claims which include pH-dependent coatings since the environmental pH changes from the highly acidic gastric environment to the more neutral to alkaline intestinal environment following gastric emptying. A final difference lies in the specificity of beneficial agents in the instant claims. However, such agents are well known for use in conjunction with controlled release osmotic delivery devices and thus it would be obvious to one of ordinary skill in the art to use such beneficial agents in the invention of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 7-8, and 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 32, 38, and 39-41 of copending Application No. 10/572502.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to a programmed drug delivery system comprising a core comprising one or more beneficial agents and one or more pharmaceutically acceptable excipients wherein at least one excipient swells when exposed to an aqueous environment, a core-surrounding coat which is impermeable to the beneficial agent but permeable or impermeable to water, a passageway in the coat, a composition applied so as to cover the passageway, and an optional immediate release composition

comprising the same or different beneficial agent. The passageway covering comprises a polymer selected from the group consisting of a water soluble polymer, a water swellable polymer, a pH-dependent polymer, and mixtures thereof. The beneficial agent can be an agent that is susceptible to the gastric environment, is targeted to the intestine for local action, or causes bleeding or irritation of the gastric mucosa. The composition covering the passageway is designed to release the core contents at a predetermined location in the gastrointestinal tract after oral ingestion. The system can provide delayed or controlled release of the beneficial agent. The system provides for either an immediate release followed by a timed controlled release of the same or different beneficial agent(s), or an immediate release of a beneficial agent followed by a delayed release of another beneficial agent, with the delays being dependent or independent of gastric emptying time.

The copending claims are drawn to a coated tablet oral drug delivery system having a core comprising at least one active ingredient and a swellable composition located in the immediate vicinity of one or more preselected surfaces, and a coating comprising water insoluble polymers and a leachable component (such as the immediate release composition of the instant claims), wherein the coating can be removed from one or more of the preselected surfaces, but not removed from at least one of the surfaces. The coating can be impermeable to the active agent or semipermeable, and an additional pH-dependent coating can be applied. Multiple layers may be present and of the same or different composition. The composition can

comprise a controlled release composition, or both immediate and controlled release compositions.

The differences in the two applications arise in the fact that the instant claims require a passageway in the coating, while the copending claims do not. However, the selective removal of the coating from one or more surfaces in the copending application functions as a "passageway" with a covering. Another difference lies in the fact that the copending claims do not explicitly require release delays being dependent on gastric emptying time. However, this feature is inherent in the copending claims which include pH-dependent coatings since the environmental pH changes from the highly acidic gastric environment to the more neutral to alkaline intestinal environment following gastric emptying. A final difference lies in the specificity of beneficial agents in the instant claims. However, such agents are well known for use in conjunction with controlled release osmotic delivery devices and thus it would be obvious to one of ordinary skill in the art to use such beneficial agents in the invention of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the use of the adjective "susceptible" requires the use a qualifying action, such as "destruction" or "dissolution". As written, one of ordinary skill in the art cannot determine the metes and bounds of the claim since its meaning can be interpreted in multiple ways. For instance, one could interpret it to mean agents which are prone to destruction and subsequent removal of beneficial action once the agent has reached the gastric environment. Another interpretation is that the claim covers all agents prone to dissolution and subsequent bioavailability upon reaction with the gastric environment. In the first case, the drug delivery system can be imagined as necessary to protect the agent until it has exited the gastric environment; in the second case, the drug delivery system can be imagined as being necessary to prevent rapid dissolution of the agent and, instead, prolong its release in the gastric environment.

Claim 5 is indefinite because the use of the words "cause bleeding or irritation" is repugnant to the generally accepted definition of "beneficial agent". One of ordinary skill in the art would be inclined to interpret the claim in multiple ways, such that the agent has another benefit besides causing bleeding or irritation and that the bleeding or irritation is a side effect the drug delivery system is designed to alleviate, or that bleeding or irritation is desired and that the agent must be selected, and the delivery system designed, such that the actions of the agent are not hindered. Thus one of ordinary skill in the art cannot readily determine the metes and bounds of the claim. For the purposes of this action, the Examiner is interpreting claim 5 as specifying an agent that has a side effect of causing bleeding or irritation of the gastric mucosa.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6491949 to Faour et. al.

The instant claims are drawn to a programmed drug delivery system comprising a core comprising one or more beneficial agents and one or more pharmaceutically acceptable excipients wherein at least one excipient swells when exposed to an aqueous environment, a core-surrounding coat which is impermeable to the beneficial agent but permeable or impermeable to water, a passageway in the coat, a composition applied so as to cover the passageway, and an optional immediate release composition comprising the same or different beneficial agent. The passageway covering comprises a polymer selected from the group consisting of a water soluble polymer, a water swellable polymer, a pH-dependent polymer, and mixtures thereof. The beneficial agent can be an agent that is susceptible to the gastric environment, is targeted to the intestine for local action, or causes bleeding or irritation of the gastric mucosa. The composition covering the passageway is designed to release the core contents at a predetermined time and location in the gastrointestinal tract after oral ingestion. The system can provide delayed, programmed, controlled, or pulsatile release of the beneficial agent. The system provides for either an immediate release followed by a timed controlled release of the same or different beneficial agent(s), or an immediate release of a beneficial agent followed by a delayed release of another beneficial agent, with the delays being dependent or independent of gastric emptying time. The system

also provides delivery of the beneficial agent to a targeted site in the form of a pulse, or in a rate controlled manner.

Faour teaches osmotic delivery devices which provide targeted, controlled, delayed, timed, or pulsatile delivery of one or more beneficial agents (same or different) from a core (or multiple cores) through a passageway in a coat, which can be covered and plugged by an immediate release layer comprised of the beneficial agent and such water soluble and water swellable polymers as polyvinylpyrrolidone, polyethylene glycol, hydroxypropyl ethylcellulose, hydroxypropyl methylcellulose, and sodium carboxymethylcellulose (column 1, lines 41-67; column 2, lines 1-8 and16-36; Figure 4; column 4, lines 32-52; column 9, lines 2-32; claims 1-54). The coat or membrane can be permeable to the influx of aqueous liquid from the surrounding environment, but requires the preformed passageways for allowing exit of the beneficial agent (column 2, lines 66-67; column 3, lines 1-10). The beneficial agent may be susceptible to the gastric environment, such as lipid-lowering niacin, targeted to the intestine for local action, such as beclomethasone, or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as aspirin or naproxen (column 14, lines 38, 43, and 58-60; column 16, lines 15-16; claims 52 and 54). Excipients for the core include those that swell upon exposure to an aqueous environment, such as an osmagent or swellable hydrophilic polymers like hydroxypropylcelluloses (column 6, lines 61-67; column 7, lines 1-16; column 9, lines 57-58; claims 21 and 25). Since Faour's invention can have multiple separate drug layers, with multiple membranes and

can release the beneficial agents in a concurrent manner (pulses), it is inherent that Faour's system produces a pulsatile release (Figure 4; column 2, lines 4-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6491949 to Faour et. al. as evidenced by US 5229131 to Amidon et. al.

The teachings of Faour are described above. Faour does not explicitly teach delivery that is dependent or independent of gastric emptying time. Faour does, however, teach that the compositions may be designed to achieve pH-dependent and pH-independent delivery of the active agent (column 5, lines 47-60).

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to create pH-dependent or pH-independent drug delivery systems with reasonable expectation of success. One would have been motivated to do so since Faour suggests the creation of pH-dependent or pH-independent embodiments of the drug delivery system.

Regarding the limitations of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon discloses that pH dependent release systems

affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus ph-dependent and ph-independent embodiments of Faour's invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH S. CAPAN whose telephone number is (571)270-5235. The examiner can normally be reached on Mon-Thurs 8:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ESC

/Sharmila Gollamudi Landau/

Primary Examiner, Art Unit 1611